

**REMARKS**

Applicants submit that the amendments made herein are fully supported in the present specification as filed and add no new matter. Further, it is respectfully requested that the present Amendment be entered into the Official File in view of the fact that the Amendment automatically places the application in condition for allowance. Applicants note that the subject matter of existing dependent claims is being incorporated into the independent claims.

If, however, the Examiner continues with the rejections of the present application, it is respectfully requested that the present Amendment be entered for purposes of an Appeal. The Amendment reduces the issues on appeal by reducing the number of claims as well as instantly overcoming the rejection under 35 U.S.C. § 102. Thus, the issues on appeal would be reduced.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

***Status of the Claims***

In the present Amendment, claims 1-3 have been amended. Also, claims 4-6 have been canceled without prejudice or disclaimer of the subject matter contained therein. Thus, claims 1-3 and 7-8 are pending in the present application.

No new matter has been added by way of these amendments as subject matter from claims 4-6 have been incorporated into claims 1-3, respectively.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

*Issues under 35 U.S.C. § 102(b)*

Claims 1-3 and 7-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by **Misaki '996** (U.S. Patent No. 4,765,996) (see pages 2-3 of the Office Action). Applicants respectfully traverse.

This rejection has been overcome as the subject matter from canceled claims 4-6 have been incorporated into the main claims. Claims 4-6 were not at issue here. Thus, reconsideration and withdrawal of this rejection are respectfully requested.

*Issues under 35 U.S.C. § 103(a)*

Claims 4-6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Misaki '996** (see pages 3-5 of the Office Action). Applicants respectfully traverse and reconsideration is based on the following remarks.

Claims 4-6 have been canceled, but such subject matter now appears in claims 1-3. Specifically, claims 1-3 now recite that “the iron salt has an average particle diameter of 2  $\mu$ m or less”. Still, the Examiner states the particle diameter feature of claims 4-6 is “recognized as being within the level of ordinary skill in the art” and cites *Gardner v. TEC Systems, Inc.*, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 225 USPQ 232 (1984) (see paragraph bridging pages 4-5 of the Office Action). Also, at pages 5-6 of the Office Action, the Examiner explains that the

unexpected results of the previously submitted Rule 132 Declaration or that in the present specification do not overcome the obviousness rejection as “selecting the size of a component is regarded as being within the ordinary level of skill in the art” (Office Action, bottom of page 6). However, case law says that such unexpected results have to be considered and not merely dismissed as a matter of “within the ordinary level of skill”. Thus, Applicants respectfully reconsideration.

Regarding the showing of unexpected results (a secondary consideration), this is one of the *Graham* factors (*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966)), and M.P.E.P. § 2143 states that a *Graham* analysis must be done. Furthermore, Applicants note M.P.E.P. § 2145:

If a *prima facie* case of obviousness is established, the burden shifts to the applicant to come forward with arguments and/or evidence to rebut the *prima facie* case. See, e.g., *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990). Rebuttal evidence and arguments can be presented in the specification, *In re Soni*, 54 F.3d 746, 750, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995), by counsel, *In re Chu*, 66 F.3d 292, 299, 36 USPQ2d 1089, 1094-95 (Fed. Cir. 1995), **or by way of an affidavit or declaration under 37 C.F.R. 1.132**, e.g., *Soni*, 54 F.3d at 750, 34 USPQ2d at 1687; *In re Piasecki*, 745 F.2d 1468, 1474, 223 USPQ 785, 789-90 (Fed. Cir. 1984). However, arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

. . . Rebuttal evidence may include evidence of "secondary considerations," such as "commercial success, long felt but unsolved needs, [and] failure of others." *Graham v. John Deere Co.*, 383 U.S. at 17, 148 USPQ at 467. See also, e.g., *In re Piasecki*, 745 F.2d 1468, 1473, 223 USPQ 785, 788 (Fed. Cir. 1984) (commercial success). **Rebuttal evidence may also include evidence that the claimed invention yields unexpectedly improved properties or properties not present in the prior art. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties.** *Dillon*, 919 F.2d at 692-93, 16 USPQ2d at 1901. **A showing of unexpected results must be based on evidence**, not argument or speculation. *In re Mayne*, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) (conclusory statements that claimed

compound possesses unusually low immune response or unexpected biological activity that is unsupported by comparative data held insufficient to overcome *prima facie* case of obviousness). . .

Also, when evidence of unexpected results is in the present specification, it is improper to not consider such evidence of patentability for the present invention. *See In re Soni*, 54 F.3d 746, 34 U.S.P.Q.2d 1684 (Fed. Cir. 1995) (error not to consider evidence in the specification); M.P.E.P. § 2144.08(II)(B).

Thus, once Applicants have presented rebuttal evidence of unexpected results, then USPTO office personnel should reconsider any initial obviousness determination in view of the entire record. Office personnel should not evaluate rebuttal evidence for its “knockdown” value against the *prima facie* case, *Piasecki*, 745 F.2d at 1473, 223 USPQ at 788, or summarily dismiss it as not compelling or insufficient. If the evidence is deemed insufficient to rebut the *prima facie* case of obviousness, USPTO office personnel should specifically set forth the facts and reasoning that justify this conclusion. It appears that the showing of unexpected results have been summarily dismissed.

Turning to the facts at hand, the cited Misaki ‘996 reference fails to disclose or suggest the enriched rice or barley having an emulsifying agent-coated iron salt composition, wherein the iron salt has an average particle diameter of 2  $\mu\text{m}$  or less, as instantly claimed. This feature does impart patentability. Applicants respectfully refer the Examiner to the previously submitted Declaration pursuant to 37 C.F.R. § 1.132 by co-inventor Noboru SAKAGUCHI as being applicable to the claims as instantly amended.

In the Rule 132 Declaration, four different examples were prepared (i.e., “Enriched Rice 1-4”). With these four examples, three different tests were conducted which measured: (1) residual ratio (%) of vitamins and minerals in the product, which is the finally prepared enriched rice (see Table I); (2) the percentage (%) of loss after washing the enriched rice (see Table II); and (3) residual ratio (%) after a one-month storage of the product (see Table III). The results for Enriched Rice 1-4 clearly shows that the Misaki ‘996 product and process are different from that of the present invention. The Misaki ‘996 embodiment (e.g., see Enriched Rice 1 or 2) leads to higher losses of vitamins and minerals, whether such losses are measured when the product was made, after washing, and after storage for one month. And again, Misaki ‘996 is prepared using iron alone. Such results are unexpected.

Furthermore, Applicants again respectfully refer the Examiner to the unexpected results shown in the present specification. When looking at the Inventive Products versus the Comparative Products M and N, enriched rice that is prepared using an emulsifying agent-coated iron salt obtained in Comparative Examples 1 and 2, the losses of vitamins are prevented (Table 1 at page 24) and the residual ratios after storage increased (Table 2 at page 25). The excellent effects are obtained because a reaction generated by a direct contact of iron and vitamins is controlled in the present invention by using an emulsifying agent-coated iron salt composition.

Thus, a proper weighing of the *Graham* factors, include evidence of secondary considerations, resides in Applicants’ favor.

Regarding the Examiner’s statement that the claimed particle size is within the ordinary level of skill in the art, Applicants respectfully traverse. Under *Ex parte Levengood*, 28 USPQ2d

1300, 1301-02 (BPAI 1993) and *Ex parte Gerlach*, 212 USPQ 471 (BPAI 1980), the Examiner cannot equate that which is within the capabilities of one skilled in the art (“one of ordinary skill in the art could adjust the parameters”) with obviousness.

Furthermore, Applicants note the specification at, e.g., page 8, lines 15-18, page 13, lines 4-6, and page 15, lines 18-20 wherein the claimed size leads to advantages such as excellent dispersibility and homogeneity. In addition, the cited *Gardner* case is directed to a different technology (e.g., a device which is especially useful in drying ink used on high-gloss papers of which many periodicals are made). The facts of that particular case do not apply to the facts for the present situation. Thus, *Gardner* is improperly applied here.

Based on the comments above and the evidence of record (e.g., the previously submitted Rule 132 Declaration), the cited Misaki ‘996 reference fails to disclose all claimed features, and the advantages of the present invention are unexpected and should be properly considered. Reconsideration and withdrawal of this rejection are respectfully requested.

### ***Conclusion***

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

*Application No. 10/542,200*

*Art Unit 1794*

*After Final Office Action of February 24, 2009*

*Docket No.: 1422-0683PUS1*

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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